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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,468	07/10/2000	Morten Sloth Weidner	030307-0220	9245

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,468	WEIDNER, MORTEN SLOTH	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10-15,17,19-21 and 23-40* is/are pending in the application.

4a) Of the above claim(s) *16 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-15,17,19-21 and 23-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt for Request for Continued Examination, Amendments, and Information Disclosure Statement filed 12/20/04 is acknowledged. Claims **1-6, 10-15, 17, 19-21, and 23-40** are pending in this application. Claims 16 and 22 are withdrawn as being directed to a nonelected invention.

Election/Restrictions

It should be noted that the examiner has rejoined claims 11-14, 17, 19-20, and 23-25 have been rejoined. Claims 11-14, 17, and 19-20 are drawn to a method for treating a disease that is related to inflammation or hypersensitivity and thus has been rejoined. Further, claims 23-25 is drawn to the method of making the pharmaceutical composition and thus has been rejoined. Claims 16 and 22 are drawn to a method of treating prostatic hypertrophy remains withdrawn.

Request for Information Rule 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

The examiner requests the natural range of triterpenes, sterols, karitenes, and the total amount of unsaponfiable material in Shea butter and also the general concentration of these components in a conventional extraction process. This information will allow the examiner to ascertain if the recited amounts are inherently present in natural Shea butter and its extracts, or if applicant's range is clearly outside the range of these natural extracts.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16, 19-22, and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *treatment* of inflammation, hypersensitivity, autoimmune disease, chronic inflammation disease, psoriasis, dermatitis, Crohn's disease, ulcerative colitis, rheumatoid arthritis, osteoarthritis, and pain respectively does not reasonably provide enablement for the *prevention* of inflammation, hypersensitivity, autoimmune disease, chronic inflammation disease, psoriasis, dermatitis, Crohn's disease, ulcerative colitis, rheumatoid arthritis, osteoarthritis, and pain respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating or preventing inflammation, hypersensitivity, autoimmune disease, chronic inflammation disease, psoriasis, dermatitis, Crohn's disease, ulcerative colitis, rheumatoid arthritis, or osteoarthritis,

and pain respectively with a pharmaceutical composition containing a triterpene fraction from butyrospermum parkii. The nature of the invention is complex in terms of prevention, in that it encompasses anticipating inflammation, the location of the inflammation, and subsequently administering instant composition such that the subject treated does not trigger immune response or manifest symptoms of inflammation.

Breath of the claims: The complex nature of the claims is greatly exacerbated by the breath of the claims. The claim to prevention would imply that all symptoms associated with inflammation, hypersensitivity, autoimmune disease, chronic inflammation disease, psoriasis, dermatitis, Crohn's disease, ulcerative colitis, rheumatoid arthritis, osteoarthritis, and pain respectively are prevented. Moreover, although the diseases listed have a common link, i.e. an inflammatory response, the various diseases that are claimed have different causes. The claim encompasses prevention of a complex autoimmune response in which all immune responses to foreign antigens are prevented which may or may not be addressed by the administration of the composition.

Guidance of the Specification: The guidance by the specification speaks on how to administer the composition to a subject in order to treat or reduce the symptoms of the respective disease. However, little or no guidance directed to preventing the respective disease is provided.

Working Examples: All of the working examples provided by the specification are directed towards the reduction of inflammation rather than the prevention of inflammatory conditions.

Predictability of the Art: The lack of significant guidance from the specification or the prior art with regard to the actual prevention of respective diseases makes practicing the instant invention unpredictable in terms of the prevention.

The State of the Art: The actual etiology of the respective diseases listed are not fully understood and the specification does not give any indication of the agent that each disease. Thus, without ascertaining the actual cause and etiology of a disease, one cannot claim to prevent the disease. See attach art of interest Lewis, et al, New targets for anti-inflammatory drugs, Curr Opin Chem Biol. 1999 Aug;3(4):489-94.

The Amount of Experimentation Necessary: In order to practice claimed invention, one of ordinary skill in the art would have to first to anticipate inflammation or hypersensitivity, its location, the effective dosage, duration of treatment, etc. to determine whether or not the instant composition prevents the disease. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art, one of ordinary skill in the art would have to either envision a modification of the variable factors or envision an entirely new combination of the factors, and test the invention again. If unsuccessful again, the whole process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-16 provide for the use of the preparation of claim 1 but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 10-16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-2, 9, 10-15, 23, 25-29, 32-33, 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/01126.

WO discloses a method of manufacturing an ester mixture. The sterol esters that are particularly suitable are those from sheanut (Butyrospermum parkii). See page 5, lines 19-25. The mixture of fatty acid sterols contains 2-45% alpha-amyrin, 0.2-25% beta-amyrin, 0.2-35%

lupeol, 2-45% butyrospermol, 0.1-15% germanicol. See page 10. The mixture is added to food products in the amount of 0.5-40%, thus this meets the limitation "at least 5% of a triterpene fraction". See page 11, lines 2-5 and page 14. The examples disclose mixing 40% ester mixture with various oils (reads on the carrier), to provide a spread.

Note that the recitation "suitable for topical administration" is an intended use limitation that is not given patentable weight since it does not provide for a structural limitation. With regard to claims 32-33, the derivation of the triterpene fraction from shea, i.e. the fraction being derived from the fruit versus bark, does not have patentable weight in a product claim unless it provides for a different product, which it does not.

Claims 1, 3, 5, 9-15, 19, 23-26, 28, 30, 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Laur et al (5679393).

Laur et al disclose a pharmaceutical composition with shea butter fractions containing triterpene alcohols and sterols and the method of making a dermatological composition containing these fractions. Laur discloses that the fractions that are enriched with unsaponfiable material contain all the native constituents of the unsaponfiable material of shea, including karitenes, triterpene alcohols, and sterols. The unsaponifiable material contains sterols, karitenes, and triterpene alcohol. See column 11-12. Generally the enriched fractions are incorporated with a pharmaceutical or cosmetic carrier in the amount of 0.5-99%. See column 5, lines 45. Further, the examples utilize an amount of 1-60% unsaponifiable a topical emulsion form containing.

Laur et al disclose the use of 30% unsaponfiable material in example 5. Thus, based on the applicant's own admission on May 23, 2003, the fraction inherently contains 4.4% butyrospermol, 10.6% amyrin, and 3.9% lupeol which satisfies the recitation of a fraction that

contains at least 2% of each component. The material also contains gums and karitenes. The fractions are extracted fro shea fruit or seed. See claim 7. Lastly, Laur discloses the anti-inflammatory properties of the shea fractions.

With regard to claim 19, it is the examiner's position that the broad claim to treatment of inflammatory disorders is met since Laur teaches the anti-inflammatory properties of the shea butter in the pharmacological and cosmetic art.

Response to Arguments

Applicant argues that the instant components are not inherent in Laur et al. Applicant argues that the arguments of May 2003 merely state how much the components would be in native shea.

Applicant's arguments have been fully considered but they are not persuasive. It is unclear if applicant is arguing that the components itself are not inherent in shea butter or that the instant amount is not inherent. Thus, the examiner cites US patent 6,399,138, column 2, lines 6-10 wherein these components are taught to be inherent in shea butter. With regard to the specific concentration, the examiner is relying on the applicant's arguments to reject the claims since applicant clearly stated in the arguments of 5/23/03, a person of ordinary skill would calculate the individual terpenes from publicly available sources and arrive at the 4.4% butyrospermol, 10.6% amyrin, and 3.9% lupeol which satisfies the recitation of a fraction that contains at least 2% of each component. The examiner previously rejected independent claim under obviousness since the claims recited "wherein said lupeol or said butyrospermol is in a weight percent in the composition ranging from 5-90%, the applicant has removed this limitation and the instant claims are anticipated.

Claim 1, 3, 5, 9-15, 19, 23-30, 32-33, and 35-40 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/63031.

WO 99/63031 discloses a fractionation process wherein the liquid fractions of shea butter have a high content of phytosterols (triterpene alcohols) that are useful for cosmetic and pharmaceutical preparations, i.e. body lotions and sunscreens. See abstract and page 8. WO teaches the fraction of shea butter contains 40% alpha-amyrin, 6% beta-amyrin, 9% lupeol, 14% butyrospermol, 5% parkeol, 4% taraxasteryl cinnamate, and other components. The triterpene alcohol fraction is in the amount of 24% (example 5-6), 22% (example 5-6), and 31.7% (example 8). The fraction also contains the sterols recited in claims 3 and 7. WO discloses the anti-inflammatory properties of the fractions. See biological tests.

With regard to claim 19, it is the examiner's position that the broad claim to treatment of inflammatory disorders is met since WO teaches the anti-inflammatory properties of the shea butter in the pharmacological and cosmetic art.

It appears that applicant is not entitled to the priority dates since the provisional does not have support for the instant ranges.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 4, 17-18, 20-21, 27, 29, 31, and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laur et al (5679393).

Laur et al teach a pharmaceutical composition with shea butter fractions containing triterpene alcohols and sterols (col. 111, lines 40-51). Laur et al teach the composition in a topical emulsion form containing 1-60% unsaponifiable material (Note examples). Laur et al also teach that the mixture may be incorporated in an amount of 0.5-99%. See column 5, lines 45. The unsaponifiable material contains sterols, karitenes, and triterpene alcohol. See column 11-12. The amount of lupeol, amyrin, sterols, and butyrospermol in the triterpene fraction are inherent (also based upon applicant's calculations on page 4 of arguments of paper no. 15). Laur et al disclose the unsaponifiable material from shea butter and other plants, have valuable properties for the fields of cosmetology, pharmacy, or medicine (col. 2, lines 29-33). Lastly, Laur et al teach the composition has anti-inflammatory activity. See column 5, lines 24-25.

Laur et al does not teach specify the higher concentrations of the individual components in the composition or the specific inflammatory diseases.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance of Laur et al and manipulate the amount of lupeol or butyrospermol

desired in the composition. One would have been motivated to do so since Laur teaches approximately 4.4% of butyrospermol and 3.9% of lupeol in one embodiment based on 30% unsaponifiable material. However, Laur et al does teach utilization of 99% of the unsaponifiable material. Thus, based on the amount of unsaponifiable material utilized the amount of the individual components will change and the prior art's teachings clearly extend into the instant range of lupeol or butyrospermol in the total composition. Further the desired concentration of each individual component depends on the nature and process of extraction and Laur et al provides the general guidance of shea butter extraction. The mere optimization of ranges of prior art conditions through routine experimentation does not support patentability of subject matter encompassed by the prior art unless there is evidence of unexpected results.

Lastly, Laur teaches the use of the compositions with the enriched unsaponfiable fractions have anti-inflammatory activities and the use of the extractions in the dermatological and pharmacological areas; thus a skilled artisan would have been motivated to utilize the shea butter containing composition for treating diseases such as instant dermatitis, psoriasis, and pain since these diseases are characterized by inflammation.

Response to Arguments

Applicant argues that Laur does not provide any motivation to increase the amount of the unsaponfiable material.

The applicant argues that the instant fraction is enriched via a certain "unique" process. However, the applicant has not provided evidence that the process of Laur and the instant application are different in fact. A careful examination of the specification demonstrates that Laur et al and applicant utilize the similar extraction procedure. On page 15 of instant

specification, applicant states that acetone is the preferred solvent and that certain solvents allow for one to select or reduce the amount of certain constituents in Butyrospermol. Further, applicant states that the instant invention provides an enriched fraction. The examiner points out that Laur et al not only utilize an acetone solvent in the examples but also emphasize enriched fractions on column 12, lines 40-45. Therefore, clearly Laur et al teaches the criticality of enriching a composition with the unsaponifiable compounds and thus provides motivation to increase the amount of the said unsaponifiable matter.

According the rejection is maintained.

Claims 17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laur et al (5679393) in view of WO 99/22706.

Laur et al teach a pharmaceutical composition with shea butter fractions containing triterpene alcohols and sterols (col. 111, lines 40-51). Laur et al teach the composition in a topical emulsion form containing 1-60% unsaponifiable material (Note examples). Laur et al also teach that the mixture may be incorporated in an amount of 0.5-99%. See column 5, lines 45. The unsaponifiable material contains sterols, karitenes, and triterpene alcohol. See column 11-12. The amount of lupeol, amyrin, sterols, and butyrospermol in the triterpene fraction are inherent (also based upon applicant's calculations on page 4 of arguments of paper no. 15). Laur et al disclose the unsaponifiable material from shea butter and other plants, have valuable properties for the fields of cosmetology, pharmacy, or medicine (col. 2, lines 29-33). Lastly, Laur et al teach the composition has anti-inflammatory activity. See column 5, lines 24-25.

Laur et al does not teach specify the higher concentrations of the individual components in the composition or the specific inflammatory diseases.

WO 99/22706 teaches a cosmetic or dermopharmaceutical composition containing plant extract of Butyrospermum parkii for treating dryness, dermatitis, eczema, sunburns, and burns. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize Laur's composition containing shea butter fractions to prevent or treat inflammation. One would have been motivated to do so since WO teaches the active components of the plant extract in Butyrospermum parkii (shea butter) are used for dermatitis, eczema, sunburns, and burns. Further, one would have expected similar results since Laur teaches the anti-inflammatory action of shea butter.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laur et al (5679393) in view of SU 1181171.

As set forth, Laur et al a composition with shea butter fractions containing triterpene alcohols and sterols, which has anti-inflammatory activity (col. 111, lines 40-51).

Laur et al do not teach Calendula officinalis in the composition.

SU 1181171 teaches the anti-inflammatory properties of the marigold plant and its extract (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add marigold extract in Laur et al's composition. One would have been motivated to do so with a reasonable expectation of at least an additive if not a synergistic effect in the composition since Laur teaches the anti-inflammatory activity of the composition and SU 1181171 teaches the anti-inflammatory properties of marigold.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
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SSG

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